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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,920	09/23/2003	David W. Morris	20366-066001; PP23362.000	2631
7590 Lisa E. Alexander Sagres Discovery, Inc. c/o Chiron Corporation P.O. Box 8097 Emeryville, CA 94662-8097			EXAMINER HARRIS, ALANA M	
			ART UNIT 1643	PAPER NUMBER
			MAIL DATE 05/30/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/669,920	<b>Applicant(s)</b> MORRIS ET AL.	
	<b>Examiner</b> Alana M. Harris, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 61,69-72,74-81 and 85-89 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 61,69-72, 74-81 and 85-89 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/07/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Request for Continued Examination***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 19, 2008 has been entered.

2. Claims 61, 69-72, 74-81 and 85-89 are pending.

Claims 82-84 and 90 have been cancelled.

Claim 87 has been amended.

Claims 61, 69-72, 74-81 and 85-89 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objection***

#### ***Claim Objection***

4. The objection of claim 67 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of Applicants' cancellation of the claim. Applicant is required to cancel the claim(s), or

amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 67 includes the broad term, cancer while depending from claim 61 that cites specific and limiting cancer types.

***Withdrawn Grounds of Rejections***

***Claim Rejections - 35 USC § 112***

5. The rejection of claims 87-89 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the cancellation of the claims.

***Claim Rejections - 35 USC § 102***

6. The rejection of claims 87-89 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application Publication number 2004/0110792 A1 (filed October 20, 2002) is withdrawn in light of Applicants' arguments.

***Claim Rejections - 35 USC § 103***

7. The rejection of claims 87-90 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication number 2004/0110792 A1 (filed October 20, 2002) is withdrawn in light of Applicants' arguments.

***New Grounds of Objection***

***Claim Objections***

8. Claim 70 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 70 includes the broad term, cancer while depending from claim 61 that cites specific and limiting cancer types.

***New Grounds and Maintained Rejections***

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 61, 69-72, 74-81 and 85-89 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. ***THIS IS A NEW MATTER REJECTION.***

Applicants claim a method for diagnosing several types of cancer, as well as the broadly termed carcinoma comprising detecting differential expression of complement receptor type 1 (CR1), wherein the CR1 gene expression is up-regulated or increased

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50%-150% relative to the control. However, this claimed method wherein the level of expression is increased and indicates any particular cancer is not set forth in the specification. Sections 0175 and 0176, bridging pages 73 and 74 of the specification note a cancer phenotype can be detected, which is not the same as detecting a particular sequence and ascribing it to a particular cancer type. While detecting expression profiles of cells in different states is contemplated there seems to be insufficient contemplation for the up-regulation of CR1 in a sample corresponds to any particular cancer.

SEQ ID NO: 1320 is mentioned in the specification in the context of several methods, however not as claimed, wherein lymphoma, carcinoma, breast or colon cancer is definitively diagnosed. The specification does disclose carcinoma associated (CA) nucleic acids can be up-regulated, as well as down-regulated in carcinomas in carcinomas, however there seems to be insufficient disclosure for SEQ ID NO: 1320 is regulated in any particular cancer, see page 26, section 0047. Applicants are requested to pointedly express where in the specification by page and section support for this claimed invention can be found or delete the new matter.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. The rejection of claims 61, 81 and 87 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention is withdrawn in view of the cancellation of the claims.

a. Claims 61, 81 and 87 cite a method for diagnosing several specific cancers, as well as carcinoma. It is art known the term, carcinoma encompasses various types of malignant neoplasms, hence the metes and bounds of the claims cannot be determined.

b. Claim 61 cites a method for diagnosing several cancer comprising detecting evidence of differential expression of complement receptor type 1 (CR1) in a patient sample, however the claim does not set forth samples from which differences are detected. Moreover, it is not clear from the claim how evidence is assessed or determined. Applicants are requested to clarify.

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 61, 71, 72, 74-76, 81, 85 and 86 are rejected under 35 U.S.C. 102(b) as being anticipated by Lanza et al. (British Journal of Haematology 77: 66-72, 1991). Lanza discloses a method of evaluating expression of a complement receptor CR1 in patient samples, see Summary and Materials...section on page 66. Peripheral blood samples were examined for type 1 complement receptor expression, see page 66,

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Materials...section; and Results on page 68. Absent evidence to the contrary the CR1 described in Lanza is the same as the CR1 corresponding to SEQ ID NO: 1320 in the claimed invention.

15. Claims 61, 71, 72, 74-76, 81 and 85 are rejected under 35 U.S.C. 102(b) as being anticipated by Guc et al. (Eur. J. Haematol 64(1): 3-9, January 2000). Guc discloses surface expression of CR1 was lower in acute myeloblastic leukemia (AML) in comparison to their normal counterparts, 5.5 fold lower. CR1 mRNA expression was significantly lower in acute lymphoblastic leukemia (ALL) than in the control group, see Abstract. Absent evidence to the contrary the CR1 described in Guc is the same as the CR1 corresponding to SEQ ID NO: 1320 in the claimed invention.

### ***Double Patenting***

16. The provisional rejection of claims 61, 69-72, 74-81 and 85-89 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 43, 44 and 49 of copending Application No. 10/573,332 (filed April 6, 2007) is maintained. Claims 67 and 90 have been cancelled.

Applicants request this "...rejection be held in abeyance until ...an indication of ...allowable subject matter" is indicated, see page 8 of the Remarks submitted of March 19, 2008. This point of view has been carefully considered, but found unpersuasive since the claimed methods from both applications have not significantly changed



substantiating withdrawal of the instant rejection. The rejection is maintained for the reason within and set forth previously in the Action mailed November 19, 2007.

17. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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12 May 2008

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643